Remarks

In the specification, the paragraph beginning at page 5, line 20, has been amended to correct a minor typographical error. No new matter is added. Support for the amendment is in the specification at page 5, lines 4-7 (emphasis added):

> In the use of odorants *to stimulate or decrease vaginal flow*, it is preferred that the subject *individual is presented with the odorant at a suprathreshold concentration* (e.g., about 25-55 decismel units), but not irritative level, and inhales the odorant for about 1-3 minutes.

Claims 1, 2, 4-6, 9-11, 35, 39-44, and 48-57 are pending. Claims 3, 7-8, 12-34, 36-38, and 45-47 have been canceled. The claims have been amended to clarify the invention as claimed. No new matter has been added.

Claim 44 and new Claims 50 and 55-57 include the limitation recited in Claim 9, i.e., a concentration up to a suprathreshold but not irritant concentration effective to alter the blood flow to the vagina of the female individual. Claim 9 having been fully considered by the Examiner, no new matter has been added with the amendment to Claim 44 or the addition of the new claims.

New Claim 53 recites administering a composition comprising an odorant mixture in a concentration up to a suprathreshold but not irritant concentration effective to alter blood flow to the vagina of the female individual. This claim clearly defines over the prior art of record for the reasons presented below, and is allowable over the cited art.

As to new Claims 48 and 49, these claims depend from and include all the limitations of Claim 43. Support for these claims is in the original claims as filed (e.g., Claim 12), and the specification. Blood flow to the vagina can be measured, for example, by use of a monitoring gauge such as a photophlethysmograph (specification at pages 7-8, bridging paragraph, and page 9, lines 5-10 and 27-28). Olfactory threshold (i.e., olfactory capacity, e.g., the magnitude of loss of smell) can be tested, for example, by administering a series of pyridine dilutions (specification at pages 5-6, bridging paragraph).[1]

No new matter has been added with the amendments to the claims, which are intended to merely clarify language used in the claims and/or the subject matter claimed, or the addition of

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[1] See also, Amoore et al., *Practical Test Kits for Quantitatively Evaluating the Sense of Smell*, Rhinology 21: 49-51 (1983), describing a set of bottles containing serial dilutions of pyridine to quantitatively test olfactory threshold and sensitivity.

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the new claims. The scope of the claims is intended to be the same after the amendment as it was before the amendment.

Rejections under 35 U.S.C. §112(2)

The Examiner rejected Claim 10 under Section 112(2) for the use of indefinite claim language. The Examiner maintains that the phrase "decismel units" is unclear in its meaning, and requires a definition of this phrase within the specification or objective evidence of its meaning within the odorant/aroma art.

Claim 10 (as amended) recites as follows (emphasis added):

> The method of claim 9, wherein the odorant composition comprises the odorants at a concentration of about 25-55 decismel units.

The Examiner states that (Office Action at page 2):

> Claim 10 is rendered vague and indefinite by the phrase "decismel units." It is unclear as to what this phrase means - e.g., this unit of measure does not appear to be recognized in the odorant/aroma art, and there does not appear to be a reasonable definition of what this phrase means with respect to actual unit of measure. Is this attempting to define a measurement involving smell receptor units and/or olfactory concentration levels and if so, how is it actually measured? It is requested that Applicant particularly point to a definition of this phrase within the instant specification, or provide objective evidence as to its meaning - e.g., within the odorant/aroma art.

It is noted that the Examiner initially rejected Claim 10 for the use of the phrase **"decismel units"** in the Office Action mailed **January 3, 2002**, at page 6, as follows (emphasis added):

> Claim 10 is rendered vague and indefinite by the phrase "wherein the concentration of the odorant is at about 25-55 decismel units" because it is unclear as to what this concentration relates to - e.g., is this the level of decismel units within each unit dosage or just a level of odorant in some initial odorant preparation from which such dosage units are prepared from?

Applicant stated in the **Response filed June 3, 2002**, at page 6, as follows (emphasis added):

> The Examiner rejected Claim 10 on the basis that it is unclear as to what a 25-55 decismel unit concentration refers to. As stated in the specification at page 5, lines 4-7 (emphasis added):
>
> ...it is preferred that *the subject individual is presented with the odorant* at a superthreshold concentration (e.g., about 25-55 decismel units), but not irritative level,...

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As further stated at page 7 of the June 3, 2002, Response (emphasis added):

> First of all, in the rejection, the Examiner asserted that the term "decismel units" "...appears to be a unit of measure seldom used in the odorant art other than by applicant..." (see, for example, the Office action at page 8).
>
> The Examiner is respectfully directed to the following patent and publication indicating the use of "decismels" as a concentration term:
>
> U.S. Patent No. 6,324,475 (Hayes et al.) at col. 8, lines 56-64, col. 20, lines 62-65, (and elsewhere).
>
> Amoore and O'Neill, *Proposal for a Unifying Scale to Express Olfactory Thresholds and Odor Levels: the "Decismel Scale,"* Olfacto-Labs, Berkeley, CA (1988), in Proceedings of the 1988 Air Pollution Control Association Annual Meeting, Paper No. 78.5 (21 pp.).
>
> The term "decismel units" is an art-recognized term that is well understood by one of ordinary skill in the odorant arts.

The term "decismel units" is an art-recognized term that is well understood by one of ordinary skill in the odorant arts. The Examiner is respectfully directed to the following patents and publications indicating the use and understanding of the term "decismels" as a concentration term.[2]

> Amoore and O'Neill, *Proposal for a Unifying Scale to Express Olfactory Thresholds and Odor Levels: the "Decismel Scale,"* Olfacto-Labs, Berkeley, CA (1988), in Proceedings of the 1988 Air Pollution Control Association Annual Meeting, Paper No. 78.5 (21 pp.).
>
> USP 5,492,934 (Hirsch) for "Chemosensory olfactory assay for somatization disorders" at col. 2, lines 49-61; col. 3, lines 19-26 and 39-57:
>
> A patient is evaluated for a chemosensory dysfunction using standard chemosensory assays known to those of skill in the art. The patient's ability to detect the type and threshold amount of a chemosensory agent by the sense of taste or smell is measured. The preferred chemosensory assays include the Smell Identification Test™, the Accusens T™ Taste Test, and unilateral threshold tests. The unilateral threshold test can be conducted by standard methods and provides for olfactory testing with any number of chemosensory agents. **The standards for unilateral threshold testing in *decismels*, including the threshold concentrations for the chemosensory agents, can be obtained from OlfactoLabs, El Cerrito, Calif.**
>
> ...
>
> The patient's threshold level for detecting a chemosensory agent is identified and compared to the known threshold values for the same sex and age group. **If the test samples containing a chemosensory agent are obtained from a commercial source, such as OlfactoLabs, El Cerrito, Calif., the samples are already calibrated in *decismels*** and no conversion from absolute threshold concentration to decismels is necessary....
>
> **Odor thresholds are expressed on the decismel scale.** The decismel scale is constructed by setting the mean threshold concentration of a chemosensory agent detected by the control

[2] The following patents/publications are enclosed herewith: USP 5,492,934 (Hirsch); USP 6,324,475 (Hayes); Prudhomme (1998); Mergler (1992); Sobel (2000). The remaining patents/publications were previously provided to the Examiner and/or available to the Examiner in USSN 09/707,655, a division of this application.

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group of 20 year olds at the 0 value. A decismel is calculated by dividing the concentration of the chemosensory agent detected by the patient by the normal threshold concentration (using the published value or empirically determining the value) and then taking the logarithm of the quotient. The logarithm of the quotient is then multiplied by 20 to obtain the decismel value. Decismel values can be positive or negative. A positive decismel value indicates the patient is less sensitive to the chemosensory agent, i.e. has a higher threshold detection concentration. A negative decismel value indicates that the patient is more sensitive to the compound, i.e. has a lower threshold detection concentration. An increase in the threshold concentration value over the mean threshold concentration value of 2-fold, corresponds to 6 decismels (or ds).

See also, USP 5,380,765 (Hirsch) for "Chemosensory olfactory assay for psychiatric disorders"

Prudhomme et al., Acute-Onset Persistent Olfactory Deficit Resulting from Multiple Overexposures to Ammonia Vapor at Work, *J Am Board Fam Pract* 11(1):66-69 (1998)

Decismels (dS) are defined as 20 log (test concentration/reference concentration), where the reference concentration is the average odor threshold in a reference population. Thus, a score of 40 dS indicates that the patient's odor detection threshold was at a test concentration 100 times the population average for the compound employed.

Mergler et al., Olfactory threshold shift following controlled 7-hour exposure to toluene and/or xylene, *Neurotoxicology* 13(1):211-5 (1992)

...Olfactory perception thresholds, **measured in decismels (ds)**, were ascertained for both toluene and PM-carbinol, contained in 100 ml bottles with serially increasing concentrations (Olfacto-Lab Kits # 191 & 11)...

Sobell et al., Sniffing Longer rather than Stronger to Maintain Olfactory Detection Threshold, *Chem. Senses* 25: 1-8 (2000)

Monorhinal detection thresholds were determined using the two-alternative, forced-choice ascending staircase method (Cain et al., 1988). Threshold was determined as the lowest concentration at which five consecutive hits were achieved. The odorants vanillin and propionic acid were diluted in deionized water **on a decismel (DS) scale dilution series** [Odorant level in DS = 20log10 (test vapor concentration/reference concentration)] (Amoore, 1992), such that average detection threshold for 30 previously tested subjects = 0 DS. For each odorant, 24 dilutions were available, starting at –45 DS up to 65 DS (5 DS increments). In all measurements, a 40 s inter-trial-interval was used, and all experimental factors were randomized and counterbalanced.

U.S. Patent No. 6,324,475 (Hayes et al.) for "Devices for Presenting Airborne Materials to the Nose" (at col. 8, lines 56-64, col. 20, lines 62-65, and elsewhere).

Each test substance/vehicle solution of interest is tested for its microdispensing performance in the test stand over a range of concentrations. For threshold testing of the sense of smell, 3-4 orders of magnitude dynamic range **(60-80 decismels)**, where:

$$1 \text{ decismel} = \frac{\log 10 \text{ [odor concentration]}}{20}$$

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USP 6,106,837 (Hirsch) for "Method of treating headaches, and article of manufacture therefor"

[Claim] 2. The method according to claim 1, wherein the concentration of the odorant is about 25-55 ***decismel*** units.

The method involves administering an effective concentration of a hedonically positive odorant ...Preferably, the subject individual is presented with the odorant at a suprathreshold concentration (e.g., about 25-55 decismel units)...

USP 5,904,916 (Hirsch) for "Use of odorants to alter learning capacity"

USP 5,885,614 (Hirsch) for "Use of odorants to treat male impotence, and article of manufacture therefor"

USP 5,759,521 (Hirsch) for "Method of altering perception of relative space of an area"

One skilled in the odorant arts would readily understand the term "decismel" as that term is used in the claims. Accordingly, it is submitted that the claims are clear in their meaning and satisfy the requirements of Section 112(2), and withdrawal of this rejection is respectfully requested.

Rejection of Claims under 35 U.S.C. §§ 102(b)/103(a) (Poan/McMath)

The Examiner rejected Claims 1, 2, 4-6, 9-10, 35, 41, 43, and 44, as anticipated by the International Product Alert bulletin entitled "Poan Washable Cold Cream Manufacture: Kurabara Honpo Category: Beauty Skin Care" (01 June 1994 - PROMT Abstract) ("Poan"), or by McMath from Adweek's Marketing Week entitled "The Skin Trade Goes Natural" (27 August 1990 - PROMT Abstract) ("McMath").

The Examiner also rejected Claims 1, 2, 4-6, 9-11, 35, and 39-44, as obvious over Poan or McMath (Office Action at page 5). The Examiner maintains that it would be obvious for a female individual to apply such skin cream products (and thus inhale the natural cucumber and licorice extract odorants contained therein) for the amount of time instantly claimed (e.g., 1-3 minutes) as this time range is considered a typical, customary time period for such topical application. The Examiner also maintains that it would be obvious to provide such female-oriented commercial skin cream products within a conventional, easy-to-use dispensable containers/vessels.

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Insofar as these rejections are maintained with respect to the claims as amended, these rejections are respectfully traversed.

First, it is noted that the Examiner assumes that the described cream products have an odor. However, neither reference describes anything about the vaporous emissions of the described product. Both Poan and McMath merely teach a cosmetic product that contains cucumber and licorice [extracts] to provide *a moisturizing effect* on the skin.

In the Office Action at pages 3-4, the Examiner states (emphasis added):

> Further, please note that the functional effects instantly claimed would be inherent to the reference odorant-containing products upon inhalation, including their ability to increase or decrease blood flow to the vagina since, as readily admitted by Applicant, women's response to odors are not homogenous and women respond differently depending on their preferences of sexual activities and behaviors; and further, odorant mixtures including, e.g., licorice-based and cucumber odorants had the effect of increasing blood flow to the vagina in some women and decreasing blood flow to the vagina in other women (see, e.g., page 16, line 23 - page 17, line 27 of the instant specification...Therefore, each of the cited references is deemed to anticipate the instantly claimed invention.

The Examiner's basis for relying on inherency to anticipate the claimed method is clearly in error.

In relying upon the theory of inherency, the Examiner must provide factual and technical grounds to support the determination that the allegedly inherent characteristic *necessarily and inevitably* results from the applied prior art. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); *Continental Can Co. USA Inc. v. Monsanto Co.*, 20 USPQ2d 1746 (Fed. Cir. 1991); *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981).

Both Poan and McMath disclose a *moisturizing* cream. For the doctrine of inherency to apply it must be inevitable that the application of the moisturizing creams of Poan and McMath *necessarily* results in an increase in blood flow to the vagina of the female.

The claims recite that the compositions contain a *concentration* of odorants that is *effective to alter blood flow to the vagina.* Neither Poan nor McMath teach or suggest a composition having such a concentration of odorants.

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The Examiner has provided no evidence or good reasoning that the application of either Poan's or McMath's product would necessarily result in an alteration in blood flow to the vagina of the female. (Rather, the Examiner's statements support a finding that Applicant's method does *not* inherently (necessarily) result from the cited references.)

Nothing in the cited references or the Examiner's statements support his allegation of inherency.

With regard to Claims 9, 44, 50 and 53-57, the Examiner maintains that the Poan and McMath products would inherently include a suprathreshold but not irritant amount of cucumber and licorice extract odors — on the basis that "the natural cucumber and licorice extract odors within the cited commercial skin creams would *inherently* be within a level *detectable by a normosmic individual* but not at a level so high or intense that it would be perceived as noxious or painful..." (emphasis added)

A "suprathreshold" amount of an odorant is *not* the level detectable by a normosmic individual. Rather, it is the concentration of the odorant that is **beyond** that needed to be detected by a normosmic individual. This is stated in the specification at page 5, lines 1-19 (emphasis added):

> An odorant is presented at a suprathreshold level when the decismel level or concentration of the odorant *is beyond that needed to be detected by a normosmic individual*. At its irritative level, the odorant quantity is so high and intense that the odorant stimulates predominantly the trigeminal nerve (for pain) rather than the olfactory nerve and, hence, is perceived as noxious or painful. The irritation threshold of the patient is the lowest concentration of the substance that causes immediate stinging or burning sensations in the nose, or stinging or lacrimation of the eye. See, J.F. Gent, in Clinical Measurement of Taste and Smell, pages 107-166, H.L. Meiselman et al. (eds.), 602 pp., MacMillan, NY (1986); R.L. Doty et al., Ann. Neurol. 25: 166-171 (1989); E. Koss et al., Neurology 38: 1228-1232 (1988); and R. Doty, The Smell Identification Test: Administration Manual 1983: 13-14, Philadelphia: Sensonics, Inc. (1983).

The Examiner is also directed to USP 5,492,934 (Hirsch) for "Chemosensory olfactory assay for somatization disorders", which also states the understanding of a "suprathreshold amount" of a chemosensory agent at col. 5, lines 5-20 (emphasis added):

> ...The kit includes at least one chemosensory agent present in a variety of concentrations ranging from sub-threshold to suprathreshold amounts for that chemosensory agent. The normal or expected threshold concentration can be a known value published by Amoore et al., cited supra., or can be determined empirically by testing a group of normal individuals with a plurality of concentrations of the chemosensory agent and calculating the means threshold concentration...A sub-threshold amount is a concentration of the chemosensory agent below

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> the normal or expected threshold concentration for that chemosensory agent. ***A suprathreshold amount is a concentration of the chemosensory agent greater than the threshold amount...***

Again, for the doctrine of inherency to apply it must be inevitable that the application of the cosmetic creams of Poan and McMath *necessarily* results in an increase in blood flow to the vagina of the female.

There is no teaching in either reference that either product contains a *suprathreshold amount* of a cucumber and licorice odorant — i.e., a concentration of the odorant that is beyond that needed to be detected by a normosmic individual. Nor is there any motivation for either product to be prepared with a suprathreshold amount (i.e., higher than normal amount) of an odorant as provided in Applicant's composition.

The Examiner has provided no evidence or good reasoning for the contention that (a) the products of either Poan or McMath inherently (necessarily) contain an effective concentration (up to a suprathreshold but not irritant concentration) of odorants, or b) the application of either product would necessarily result in an alteration in blood flow to the vagina of the female.

Furthermore, even if a composition is old, a process using a known composition in a new and unobvious way may be patentable. *Loctite Corporation v. Ultraseal Ltd., et al.*, 228 USPQ 90 (Fed. Cir. 1985); *In re Zierden*, 162 USPQ 102, 104 (CCPA 1969). A new use of a known material is claimed in the form of a process or method. There is express statutory authority for a patent on a process that is a new use of a known process, composition of matter, or material, under 35 U.S.C. §100(b) ("The term "process" means process, art or method, and includes *a new use of a known* process, machine, manufacture, composition of matter, or *material*." (emphasis added)).

If the result of the process is unobvious and the particular use of the material is not suggested by the prior art, the process is patentable. *Ex parte Wagner*, 88 USPQ 217, 220 (Bd. Pat. App. & Int. 1950). *In re Shetty*, 195 USPQ 753 (CCPA 1977) (claim to compound unpatentable as obvious in light of structurally similar compounds in prior art; *claim to "method of curbing apperite* in an animal which comprises administering to the animal an amount effective to curb appetite" of the compound *not obvious*: none of the similar compounds "suggested a use, much less a dosage, for curbing appetite").

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Thus, even if a composition containing cucumber and licorice extract odors may have been known in the art, there is absolutely nothing in either of the cited references that would lead one skilled in the art to attempt to alter blood flow to the vagina by administering a composition of odorants according to the present method.

Nothing in the cited references remotely suggests administering a composition comprising an odorant according to the present method to alter blood flow to the vagina of a female individual. Nor is there anything in the cited references that supports the Examiner's assertion that applying the products of the cited references would inherently result in Applicant's method to alter blood flow to the vagina of a female individual.

Accordingly, withdrawal of the rejection of the claims based on the cited references is respectfully requested.

Rejection of Claims under 35 U.S.C. § 102(b) (Yankee Candle)

The Examiner rejected Claims 1, 2, 4, 5, 9-11, and 44, as anticipated by candle products on display within a Yankee Candle Company, Inc. store, citing to the internet website http://www.yankeecandle.com/cgi-bin/ycbvp/ycContent.jsp?page=/About+Yankee+Candle/About+Us+Home, with a print-out date of September 27, 2004. Insofar as this rejection is maintained with respect to the claims as amended, this rejection is respectfully traversed.

The Examiner states that the Yankee Candle Co. has been in business since 1969, and its products have been sold in franchise stores within malls since 1989. However, the print-out date of the cited reference material is *September 2004*.

The Examiner has provided no credible evidence of the actual products sold *in mall stores* prior to Applicant's filing date of December 14, 1998. The list of fragrances provided by the Examiner are the fragrances that are *currently* available *on-line* through the website. The reference does not provide any indication of fragrance candles that were actually provided in a Yankee Candle store prior to Applicant's invention.

Furthermore, the list of fragrances does not include either "licorice" or "chocolate" — nor does the list include any of the recited compositions (i.e., mixtures of licorice and cucumber odorants, or licorice and banana nut bread odorants, or lavender and pumpkin pie odorants, or baby powder and chocolate odorants).

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The Examiner has provided no evidence from the cited reference of the recited odorant compositions and mixtures of odorants. Yankee Candle lists a number of fragrances — but not the mixtures recited in the claims.

As for the basis of the Examiner's rejection of the claims, the Examiner asserts that a female customer in a Yankee Candle Co. store would inhale the scented candle fragrances in the store, and the effects of Applicant's method would *inherently* occur upon such inhalation by the female customer.

As stated above, in relying upon a theory of inherency, the Examiner must provide factual and technical grounds to support the determination that the allegedly inherent characteristic *necessarily* results from the applied prior art. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [See cited cases above.]

The mere presence of a large number of fragrances that *may* be in the air within a candle store and a female shopper generally inhaling those fragrances would not *inherently* (necessarily) result in (a) the inhalation of the mixture of odorants as recited in the claims, or (b) an increase in blood flow to the vagina of the female shopper.

The Examiner has not provided any evidence — other than mere speculation — that the inhalation by a female customer while in a Yankee Candle store would *necessarily* result an increase in blood flow to her vagina.

There is nothing in the cited Yankee Candle reference that remotely suggests administering an odorant composition according to the present method to alter blood flow to the vagina of a female individual. Nor is there anything in this reference that supports the Examiner's assertion that a female customer inhaling candle fragrances in a candle store would inherently (necessarily) result in Applicant's method to alter blood flow to the vagina of the female individual.

Accordingly, withdrawal of the rejection of the claims based on the Yankee Candle reference is respectfully requested.

Extension of Term. The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that no extension of term is required.

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However, if an extension is required, please consider this a petition therefor and charge the required fee(s) to Account No. 23-2053.

Applicant believes that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is urged to telephone the undersigned Attorney if any questions should arise or further discussion would expedite the examination of the application.

Respectfully submitted,

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Dated: January 13, 2005

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